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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,655

05/01/2006

Kazuhiro Machida

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EXAMINER

EPPS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

04/15/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,655	<b>Applicant(s)</b> MACHIDA ET AL.	
	<b>Examiner</b> Janet L. Epps-Smith	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,12 and 14-31 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,12,14-16 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-21-10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/2009 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 3-6, 12, and 14-31 are pending.
4. Claims 3, 6, 12, 14-16, and 24-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
5. Claims 1, 4-5 and 17-23 are presently under examination.

### ***Claim Rejections - 35 USC § 112***

1. Claims 1, 4-5, and 21-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.
2. Applicant's arguments filed 11-23-2009 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the disclosure of PsmA, BpmA, and TpmA which share a high degree of conserved amino acids, is sufficient to demonstrate that Applicant's specification adequately complies with the written description requirement. The Examiner agrees that the specification

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provides adequate written description for a DNA encoding a protein having enzymatic activity to hydroxylate the 16-position of the macrolide compound 11107B, wherein the DNA has “a nucleotide sequence having 90% or more identity over the full length sequence of nucleotides 1322 to 2548 of SEQ ID NO: 1. However, the scope of the instant claims encompass DNA molecules which comprise *a nucleotide sequence* having 90% or more identity over less than the entire sequence of nucleotides 1322 to 2548 of SEQ ID NO: 1. The specification as filed does not provide adequate support for DNA encoding a protein having enzymatic activity to hydroxylate the 16-position of the macrolide compound 11107B, wherein said sequence has 90% or more identity over less than the entire sequence of nucleotides 1322 to 2548 of SEQ ID NO: 1.

3. The rejection of claims 18 and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's submission of a new sequence listing.

#### ***Claim Objections***

4. Claims 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-5 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakajima et al. (WO2003040370A1, in Japanese, see English publication US2005/0084859 A1).

7. Claim 1 recites a DNA participating in biological transformation of a macrolide compound, the DNA being an isolated and pure DNA comprising a DNA encoding a protein having enzymatic activity to hydroxylate the 16-position of the macrolide compound 11107B, wherein the DNA has "a nucleotide sequence having 90% or more identity with nucleotides 1322 to 2548 of SEQ ID NO: 1. It is noted that the instant claims do not require 90% identity over the full length sequence of nucleotides 1322 to 2548 of SEQ ID NO: 1.

8. Nakajima et al. discloses the nucleotide sequence of SEQ ID NO: 237, which encodes an herbicide metabolizing protein. This nucleotide sequence has an overall identity of 85.5% identity with nucleotides 1322 to 2548 of SEQ ID NO: 1 of the instant application. However, there are multiple nucleotide sequences of SEQ ID NO: 237 that comprise 100% identity to nucleotides 1322 to 2548 of SEQ ID NO: 1. SEQ ID NO: 147 and 148 also share at least 84% identity to nucleotides 1322 to 2548 of SEQ ID NO: 1, and further comprise multiple nucleotide sequences having 100% identity to nucleotides 1322 to 2548 of SEQ ID NO: 1.

9. Nakajima et al. discloses a vector comprising the disclosed sequences, and transformants comprising said vector (see claims).

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10. Absent evidence to the contrary, this disclosure of Nakajima et al. reads on the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633

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